

Application No. 09/996,838  
Attorney Docket No. P 23,643-A USA

October 25, 2007  
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### REMARKS

Applicants request respectfully that the allowability of the claims be reconsidered in view of the above amendments and the following remarks.

#### Status of the Claims

The Examiner's Action addressed Claims 1, 7, 11, 14, 15, and 18 to 32. Claims 18 to 32 are canceled. Claim 1 is amended. Accordingly, the claims pending presently for examination are Claims 1, 7, 11, 14, and 15.

#### Summary of Examiner Interview

Applicants gratefully acknowledge the Examiner's interview with applicants' attorney, Marc Segal, on October 24, 2007.

In order to advance prosecution of the process claims, applicants agreed to cancel Claims 18 to 32 directed to a stable colloid and methods of using the claimed stable colloid without prejudice to pursuing such claims in a continuation.

With respect to the process claims (Claim 1 and its dependent claims), it was agreed that only a new matter rejection remains pending. Applicants' attorney agreed to replace "consists essentially of" with "consists of" to address the Examiner's objection to the "consists essentially of" recitation in Claim 1. Regarding the Examiner's objection to the "sequestered within" recitation in Claim 1, applicants' attorney pointed out to the Examiner that such language was suggested by the Examiner during a prior Examiner interview on April 25, 2007, and that such language

was supported in the specification, particularly at paragraph 35 of the published application. After reviewing pertinent portions of the specification, the Examiner agreed that there was support for the “sequestered within” recitation and that the new matter rejection based on this recitation would be withdrawn. If the above amendment regarding “consists essentially of” is made, the Examiner indicated that the process claims would be in a condition for allowance.

Applicants agreed to file an RCE with the proposed claim amendment prior to November 1, 2007.

#### Discussion of the Amendments

Claim 1 has been amended to replace the recitation “consists essentially of” with “consists of.” No new matter has been added.

Claim 11 has been amended to be consistent with Claim 1.

Claims 18 to 32 have been canceled.

#### Discussion of the Examiner’s Section 102(e) Rejection of Claims 18 to 23 and 30 Based on Monahan et al.

The Examiner has rejected Claims 18 to 23 and 30 as being anticipated under Section 102(e) by Monahan et al. (U.S. Patent No. 6,379,966). Claims 18 to 32 have been canceled. Accordingly, this rejection is now moot.

Discussion of the Examiner's Section 112 Rejection

The Examiner has rejected Claims 1, 7, 11, 14-15, 18-23, and 24-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner indicated that this is a new matter rejection.

With respect to the presently pending Claims 1, 7, 11, 14, and 25, the Examiner asserts that (1) the specification as filed does not provide adequate support for the "consisting essentially of" recitation as the specification as filed does not describe what constitutes "a material change in the basic and novel characteristics of the invention" (Action at p. 6) and (2) "the specification as filed does not provide adequate support for the claimed process, wherein the process is initiated with DNA sequestered within the DNA/cationic lipid or liposome complex, and wherein said complex is subsequently treated with citraconic anhydride or N-hydroxysuccinimide ester." (Action at p. 5-6).

In regards to the "consisting essentially of" recitation in Claim 1, Applicants have amended Claim 1 to replace the recitation "consists essentially of" with "consists of." Accordingly, this portion of the Examiner's rejection is now moot.

In regards to the "sequestered within" recitation in Claim 1, the specification adequately supports the claimed process, wherein the process starts with a DNA complex which consists of DNA *sequestered within* cationic lipids or cationic

polymers, and the DNA complex is reacted with citraconic anhydride or N-hydroxysuccinimide to reduce, remove or reverse the cationic surface potential of the complex.

For example, in paragraph 35 of the published application, the specification provides that “stable particles containing active plasmid DNA can be produced using a self-assembling process where cationic lipids or cationic lipid/neutral lipid mixtures are attached to DNA by ionic interactions.” The specification provides that “if enough lipid is used, all of the DNA becomes *sequestered within* the lipid structure and is unavailable to compounds in solution such as DNase.” *Id.* at ¶ 35 (emphasis added). The specification further provides that the lipid structure (surrounding the DNA) is then chemically modified to reduce or reverse the cationic potential of the DNA complex as recited in Claim 1.

The process of the present invention takes advantage of this self-assembling system to package the DNA [i.e., sequester the DNA], but adds a chemical modification of the lipids to reduce or reverse the zeta potential. The DNA remains in its convenient protective package, that is, enveloped in lipids [i.e., the DNA is sequestered within lipids]. The result is that a cationic lipid is used to package DNA in a complex, which is subsequently altered to form a neutral or anionic colloid in which the DNA is still present.

Specification at ¶ 35.

Accordingly, it is clear that the specification discloses that DNA may be sequestered within cationic lipids to form a DNA complex before the cationic lipids (which are now part of the complex) are chemically modified to reduce, remove, or reverse the cationic surface potential of the complex. Thus, this new matter rejection should be withdrawn.

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CONCLUSION

In view of the foregoing amendments and remarks, applicants assert that the claims are in condition for allowance and request respectfully issuance of a Notice of Allowance.

This Reply is being submitted along with the requisite fee for filing an RCE. If any additional fees are required to continue the prosecution of this application, please charge such fees to Deposit Account 19-5425.

Respectfully submitted,

/Marc S. Segal/  
Marc S. Segal  
Registration No. 40,163

SYNNESTVEDT & LECHNER LLP  
1101 Market Street, Suite 2600  
Philadelphia, PA 19107  
(215) 923-4466 - Telephone  
(215) 923-2189 - Facsimile